§ 627.37

§627.37 Importation directives.

Importation of etiologic agents is subject to the Public Health Service Foreign Quarantine Regulations (42 CFR 71.156). Examples of permits authorizing the importation or receipt of regulated materials and specifying conditions under which the etiologic agent is shipped, handled, and used are contained in appendix E to this part.

§627.38 Shipment directives.

Shipping unmarked and unidentified etiologic agents is prohibited. Etiologic agents will be packaged, labeled, and shipped according to the requirements found in the Interstate Shipment of Etiologic Agents Regulations (42 CFR part 72) and its amendments. The USDA regulations in 9 CFR parts 102 through 104, 122 and the FDA regulations in 21 CFR parts 312 and 600 through 680 will also be followed as applicable. Packaging and labeling requirements for interstate shipment of etiologic agents are summarized and illustrated in appendix D. Permits authorizing the shipment of regulated materials and specifying conditions under which the etiologic agent is shipped, handled, and used are contained in appendix E to this part.

§627.39 Transportation directives.

The packaging and labeling requirements cited above must be followed for the local transport of etiologic agents and diagnostic specimens by courier or by other delivery services. Similar requirements and restrictions applicable to the transport of etiologic agents, diagnostic specimens, and biological products by all modes of transportation (that is, air, motor, rail, and water) are imposed by the Department of Transportation (49 CFR part 173), IATA "Dangerous Goods Regulations," the Air Transport Association "Restricted Articles Tariff 6-D," the International Civil Aviation Organization (ICAO), Postal Bulletin No. 21246 'International Mail-Hazardous Materials," 39 CFR, and, the Domestic Mail Manual. When shipments exceed 4 liters, the requirements found in AR 740-32 will be followed.

§627.40 Additional requirements.

Additional requirements for importation, shipment, and transportation of infectious agents and hazardous materials that must be followed are contained in the following directives:

- (a) AR 40–12, Medical and Agricultural Foreign and Domestic Quarantine Regulations for Vessels, Aircraft, and Other Transports of the Armed Forces.
- (b) AR 70-65, Management of Controlled Substances, Ethyl Alcohol, and Hazardous Biological Substances in Army Research, Development, Test, and Evaluation Facilities.

§ 627.41 Sources for further information on shipment of etiologic agents.

- (a) Guide for Transportation of Hazardous Materials, Vol. 4(1), February 10, 1975. Copies are obtainable from the Office of Research Grants Inquiries, NIH, Department of Health and Human Services, 5333 Westbard Avenue, Bethesda, MD 20205.
- (b) The CDC, Office of Biosafety, 1600 Clifton Road N.E., Atlanta, Georgia 30333. Telephone (404) 639–3883, or FTS: 236–3883.
- (c) The American Type Culture Collection (ATCC), Packaging and Shipping of Biological Materials at ATCC. Copies may be obtained from the ATCC, 12301 Parklawn Drive, Rockville, MD 20852. Phone (301) 881–2600.
- (d) National Committee for Clinical Laboratory Standards (NCCLS), Procedures for the Domestic Handling and Transport of Diagnostic Specimens and Etiologic Agents, (H5-A2), Second edition. Vol. 5, No. 1. Copies are obtainable from the NCCLS, 771 East Lancaster Avenue, Villanova, PA 19085.

Subpart G—Facilities

§627.42 Introduction.

The design of the facility is important in providing a secondary barrier to protect individuals inside and outside the facility. Because the hazards presented by various organisms and materials vary, the requirements for the facility will vary accordingly. The minimum facility requirements for the various biosafety levels and toxins are described below. The biosafety levels correspond to those described in the